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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,561	12/03/2003	Gudmundur Fertram Sigurjonsson	SIGU3004/JEK/JJC	3999

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ALEXANDRIA, VA 22314

EXAMINER
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LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3772

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/22/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/725,561

Applicant(s)

SIGURJONSSON, GUDMUNDUR  
FERTRAM

Examiner

Kim M. Lewis

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-23 and 29-31 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-9, 11-19 and 24-28 is/are rejected.
- 7) ☒ Claim(s) 6, 10 and 20 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 12/3/03, 7/29/04, 8/13/04, 2/4/05
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☒ Other: Detailed Action

## **DETAILED ACTION**

### ***Information Disclosure Statement(s)***

1. The information disclosure statement filed 12/3/03, 7/29/04, 8/13/04 and 2/1/05 have been received. Note the acknowledged PTO-1449 forms enclosed herewith.

### ***Response to Amendment***

2. The preliminary amendment filed on 7/29/04 has been received and made of record. As requested claim 7 has been amended and claims 21-31 have been added.
3. Claims 1-31 are pending in the instant application.

### ***Drawings***

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "w" is missing from Fig. 2, note page 8, lines 15-17. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "86" located in Fig. 12 is not in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

3. The disclosure is objected to because of the following informalities:

Fig. 12, which represents a facing layer, is not described in the detailed description of specification;

In Figs. 25-28, projection elements appear to be indicated by reference character "57" not "56" as recited in the specification on page 34, lines 20-30 and page 35, line 4;

Page 29, line 19, "43" should read --47--;

Page 31, line 20, "43" should read --47--; and Page 32, line 28, "the needles" should read --the projection elements-- since they were previously defined as such.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 20 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. More specifically, the recitation that "the elastomeric gel layer only extends into surface irregularities of the absorbent core" is not disc .

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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6. Claims 1-5, 7-9, 15, 17-19 and 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,207,875 ("Lindqvist et al.").

As regards claims 1 and 24, Lindqvist et al. disclose a wound dressing that anticipates applicant's presently claimed invention. More specifically, as can be seen in Fig. 2, Lindqvist et al. disclose a wound dressing (7) comprising an absorbent core (2') having opposed proximal and distal surfaces and a discrete skin adherent, elastomeric gel layer (3') disposed along the proximal surface of the absorbent core, said elastomeric gel layer having a plurality of through extending apertures arranged in a pattern and formed by the gel extending into holes (6) in the absorbent core.

As regards claim 2, Lindqvist et al. disclose the wound dressing according to claim 1, wherein a proximal surface of the elastomeric gel layer is substantially planar. (note Figs. 2 and 2A)

As regards claim 3, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the elastomeric gel layer is directly applied to the proximal surface of the absorbent core (note col. 2, lines 46-49).

As regards claim 4, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the apertures have a generally circular cross-section (note Figs. 2 and 2A).

Regarding claim 5, as can be seen from Fig. 2, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the pattern of apertures comprises an array of equally spaced apertures. Also, note col. 4, lines 45-48.

As regards claim 7, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the elastomeric layer comprises a cross-linked silicone gel (note col. 3, lines 19-20).

As regards claim 8, Lindqvist et al. disclose the wound dressing according to claim 7, wherein the apertures are generally uniform in size (col. 6, lines 31-32)..

As regards claim 9, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the elastomeric gel layer penetrates surface irregularities along the proximal surface of the absorbent core (note Fig. 2A).

As regards claim 15, Lindqvist et al. disclose at col. 4, line 67-col. 5, line 2, apertures that may vary in size.

As regards claim 17, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the elastomeric gel layer has regions of varying thickness since the open cells are not uniform across the foam.

As regards claim 18, Lindqvist et al. disclose the wound dressing according to claim 1, wherein the absorbent core comprises a hydrophilic polyurethane foam with a plurality of open pores along the proximal side thereof (col. 3, lines 7-14).

Regarding claim 19, as can be read from the disclose, Lindqvist et al. inherently disclose the wound dressing according to claim 18, wherein the elastomeric gel layer bridges said open pores of the absorbent core.

Regarding claim 25, as can be read from col. 6, lines 31-34, the holes are formed uniformly, thereby having a uniform shape.

As regards claim 26, note the rejection of claim 5 above.

Regarding claim 27, note the rejection of claims 1 and 24 above. In further regard to claim 27, the gel layer discussed above in the rejection of claims 1 and 24 is a facing layer since it faces the skin of the user during use. Applicant should also note that the facing layer consists of the gel layer.

As regards claim 28, note rejection of claims 25 and 27 above.

### ***Claim Rejections - 35 USC § 103***

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al. in view of U.S. Patent No. 5,340,363 ("Fabo")

As regards claim 11, Lindqvist et al. fail to teach that the elastomeric gel comprises at least one additive. However, Fabo discloses a wound dressing comprising an elastomeric gel layer having an anti-bacterial agent therein for the inherent purpose of preventing and/or killing bacteria at the surface of the wound onto which the dressing is applied.



In view of Fabo, it would have been obvious to one having ordinary skill in the art to add an anti-bacterial agent to the elastomeric gel in order to prevent and/or kill bacteria at the surface of the wound onto which the dressing is applied.

9. Claims 12-14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindqvist et al.

As regards claims 12-14 and 16, Lindqvist et al. fail to teach that the pattern of apertures of the elastomeric gel layer is defined as varying in number per unit area relative to their position to a central axis of the absorbent core, that the apertures vary in size according to their location relative to a position of each of said apertures to a central axis of the absorbent core, that the number of apertures per unit area corresponding to a central portion of the absorbent core is greater than at portions corresponding to the absorbent core located outside the central portion, and that the pattern of the apertures is defined as arrays of alternating apertures of at least two different sizes..

Lindqvist et al., however, disclose at col. 4, line 67-col. 5, line 5, that the absorption rate of the dressing can be varied by varying the density of the hole pattern and the size of the holes, and that the hole pattern increases the flexibility of the dressing. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to vary the arrangement of the holes and size of the holes in the absorbent foam, thereby varying the arrangement and size of the holes in

the gel, in order to achieve a desired effect (e.g., increase the absorption rate, increase flexibility, etc.).

***Allowable Subject Matter***

10. Claims 21-23 and 29-31 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Monday to Friday, from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Kim M. Lewis

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Primary Examiner  
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kml  
December 21, 2006